Biological Risk Analysis: Risk assessment and management options for imports of swine and swine products from the European Union -

June 2, 1999

United States Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services
Policy and Program Development

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Executive Summary

Classical swine fever (CSF), also known as hog cholera, is a highly contagious disease of swine which is exotic to the United States (US) (1). The disease was eradicated from the US in 1976 after a 16 year effort which cost the United States Department of Agriculture (USDA) and individual States approximately $140 million (1976 dollars) (2). Today this program would cost about $525 million (1997 dollars).

To prevent the reintroduction of CSF into the US, the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) has historically prohibited the importation of swine from any country affected with CSF. This prohibition applied to the entire country, even though CSF might occur in only a part of that country. Similarly, the importation of products derived from swine (e.g., pork) was prohibited from the entire country unless the products were processed in a manner known to inactivate the virus of CSF.

Recently, however, APHIS has changed its import requirements to incorporate the concepts of regionalization and risk assessment. The new approach to the importation of animals and animal products recognizes that regions defined by borders other than national boundaries may present different levels of animal disease risk. This approach is consistent with APHIS' obligations under the North American Free Trade Agreement and the World Trade Organization sanitary and phytosanitary agreements, and provides the basis for the present analysis of the risk of introducing CSF into the US by way breeding swine, swine semen, and fresh pork imported from a region identified within the European Union (EU).

The European Commission (EC) requested the United States (US) to recognize certain European Union (EU) regions as areas in which Classical Swine Fever (CSF) is not known to exist. This request was made so that the EU could export breeding swine, swine semen, and pork and pork products from these regions to the US. Without US recognition on a regional basis, these regions would be considered affected by CSF. Since CSF is exotic in the US, importation of swine or untreated swine products from the EU would be prohibited under current US regulations.

In response to the EC request, APHIS performed a quantitative risk assessment to estimate the probability that CSF would be imported with breeding swine, swine semen and fresh or frozen pork from the EU. The analysis of live animals was limited to breeding swine since the importation of other live swine was not considered cost-effective.

The risk assessment considered epidemiological characteristics of CSF in the EU. Epidemiological data suggested that the disease spread through movement of domestic animals

(primarily pigs for fattening or slaughter), transmission from wild boars, or from movement of people, vehicles or equipment contaminated with virus. The EU provided documentation on veterinary infrastructure and regulations, movement controls, physical and epidemiological characteristics of the region, disease status in the regions and adjacent regions, disease control programs, control of animal and product movement, livestock demographics and marketing practices, and disease surveillance in the context of disease epidemiology in the EU. Input variables for the quantitative assessment were derived from these data.

The information submitted by the EU identified the conditions imposed by its existing regulations, which are harmonized and binding on all Member States. Relevant EU regulations on live animals describe internal veterinary certifications and define procedures for management of outbreaks (including a stamping-out policy). Swine semen exported from the EU to the US originates from donor boars held in isolation for at least 30 days prior to entering a federally inspected semen collection center and tested as negative during that period with a test for CSF approved by the Office International des Epizooties.

APHIS evaluated the risk of introduction of CSF into the US under the following starting import conditions: that (1) swine and swine semen be accompanied by a certificate of origin stating that the animals must not have lived in a region listed at that time as one in which hog cholera is known to exist; (2) the animals must not have transited such a region unless they were moved directly through it in a sealed means of conveyance with the seal intact at the point of destination; (3) they must not have been commingled with swine which have been in a region in which hog cholera is known at that time to exist; and (4) no equipment or materials used in transporting the swine or donor boars may have been used for transporting animals ineligible for export to the US prior to appropriate cleaning and disinfection.

Under these conditions, the starting risk level of CSF introduction into the US by breeding swine from the EU was estimated as one or more outbreaks in 33,670 years. No additional mitigations were assessed. The starting risk level of CSF introduction by swine semen was one or more outbreaks in 1,842 years. The mitigating effects of holding semen donor boars and observing them clinically for 40 days after semen collection reduced this likelihood to one or more outbreaks in 257.7 million years. The starting likelihood of CSF introduction by pork was one or more outbreaks in 22,676 years. No additional mitigations were assessed.

These estimates have been used to develop recommendations to the APHIS Administrator regarding relevant regulation changes.

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Introduction

Classical swine fever (CSF), also known as hog cholera, is a highly contagious disease of swine which is exotic to the United States (US) (1). The disease was eradicated from the US in 1976 after a 16 year effort which cost the United States Department of Agriculture (USDA) and individual States approximately $140 million (2). Today this program would cost about $525 million (1997 dollars).

To prevent the reintroduction of CSF into the US, the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) has historically prohibited the importation of swine from any country affected with CSF. This prohibition applied to the entire country, even though CSF might occur in only a part of that country. Similarly, the importation of products derived from swine (e.g., pork) was prohibited from the entire country unless the products were processed in a manner known to inactivate the virus of CSF. Recently, however, APHIS has changed its import requirements to incorporate the concepts of regionalization and risk assessment. The new approach to the importation of animals and animal products is described in a policy statement (3) and regulatory changes (4) published in 1997, and recognizes that regions defined by borders other than national boundaries may present different levels of animal disease risk. This approach is consistent with APHIS' obligations under the North American Free Trade Agreement and the World Trade Organization sanitary and phytosanitary agreements, and provides the basis for the present analysis of the risk of introducing CSF into the US by way breeding swine, swine semen, and fresh pork imported from a region identified within the European Union (EU).

Description of Request and Action Taken

APHIS received a request from the European Commission (EC) for recognition of the animal health status of Member States and their regions with respect to CSF. The EC considers all of the EU to be free of CSF except for specific regions on which restrictions have been placed because of outbreaks the disease. Recognition of free areas, as defined by the EC, would enable those areas to export swine and swine products to the US. A map showing the EU Member States is provided as Figure 1 for reference.

The EC and individual Member States submitted extensive documentation in support of this request. Copies of this documentation is available on the Internet (6).

APHIS personnel evaluated the information received from the EU on outbreak history and epidemiology (6) in the context of disease characteristics. Possible sources of hazard were identified and the effectiveness of control measures in the EU was evaluated.

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This report presents APHIS's assessment of the risk of introducing CSF into the US by way of breeding swine, swine semen, and fresh and frozen pork imported from the EU under the existing conditions imposed by EC regulations. In addition, the impact of certain import requirements (mitigations) for reducing the potential risk of introducing CSF into the US was determined.

Identification of Hazards Associated with CSF in the EU

APHIS identified hazards in the context of an Office International des Epizooties (OIE) definition of a CSF free country (5). This definition states that a country may be considered free of CSF if the disease has not been detected for six months and the country practices a stamping-out policy without vaccination. Using this definition, APHIS defined regions of the EU, based on the history of disease transmission (6) and epidemiology.

CSF is spread in the EU by three principal means: (a) exposure to infected wild boars, either through contact or by garbage feeding; (b) movement of infected domestic swine; and (c) movement of people and equipment contaminated with CSF virus (6). A summary of the outbreak history in various countries is presented in Table 1.

APHIS excluded certain regions of high risk from the analysis. These high risk regions fell into two categories: (1) the area experienced one or more outbreaks of CSF in domestic swine in the past six months, or (2) evidence exists that CSF exists in wild swine in the region and that the wild swine have been a source of infection in domestic swine. These regions are identified on the map in Figure 2.

Specifically, CSF is known to be endemic in wild swine in northern Germany and Italy, and possibly in some alpine areas in Austria and France (6). Recent outbreaks in Germany have been attributed to spread from wild swine. Those regions of Germany where outbreaks associated with spread from wild swine were considered high risk and excluded from this analysis. However, despite the reservoir of infection in wild swine in France and Austria, there is no history of recent outbreaks where disease appeared to be transmitted from wild to domestic swine. Therefore, APHIS included the wild swine areas of France and Austria in the analysis.

In 1997 and 1998, there was a great deal of swine movement between EU Member States and within Member States (6). Swine born in one Member State are routinely fattened or slaughtered in another. In 1995, approximately 3.8 million pigs moved from one Member State to another for fattening, and 3.9 million pigs moved from one Member State to another for slaughter.

Outbreaks of disease in domestic pigs have occurred at least once in every year since 1993 in one or more Member States (6 and summarized in Table 1). Although some of the outbreaks were attributed to transmission from wild boars, others were attributed to movement of infected

domestic pigs and/or movement of people and equipment. The source of some outbreaks was not determined.

Table 1. CSF Outbreaks in EU Member States since 1993.

1993	1994	1995	1996	1997	1998
Germany	Germany	Germany	Germany	Germany	Germany
Italy	Italy	Italy	Italy	Italy	Italy
Belgium	Belgium			Belgium	
France					
	Austria	Austria	Austria		
				Netherlands	
				Spain	Spain

The EU stamping out policy requires the establishment of protection and surveillance zones around an outbreak. These are zones (which will be defined more completely in the following section on EU control mechanisms) in which disease control measures have been initiated and movement of animals is prohibited. An outbreak of particular concern was one that occurred in the Netherlands in 1997. Movement of infected fattening pigs spread disease to other countries, including Spain, in 1997. The epidemiological evidence surrounding this outbreak and its subsequent spread suggested that the stamping out policy was not effective. The circumstances surrounding this case were considered as a "worst case scenario" in APHIS's risk considerations.

Disease occurring outside of protection and surveillance zones would be more likely to spread than disease inside one of these zones since the level of control is limited outside. For that reason, in this assessment we identified a "risky period" associated with outbreaks occurring outside of specially controlled areas, i.e., outside of established protection and surveillance zones. The "risky period" was defined as the time from infection to the time the stamping outs policy was enforced. In 1997, an estimated 103 of 611 outbreaks were identified which occurred outside of any established protection and surveillance zones in the EU. The regions where infected herds were found outside of surveillance and protection zones in this outbreak are illustrated in Figure 3. Information from these outbreaks was used to evaluate duration of the "risky period" for application in the model.

Analysis of data submitted by the EU (6) revealed that the length of the risky period varied with each EU Member State. Epidemiological evidence suggested the disease was present in various regions from seven days to nearly eight weeks before it was detected and the region began the

stamping out process. These estimates are incorporated into APHIS's assessment of risk. Supporting data for them will be discussed subsequently in the context of the model.

The type of swine operation was also taken into account in the assessment of risk. Of the 103 outbreaks occurring outside of specially controlled areas, only one was a breeding swine operation and one was a swine semen center that engaged in export sales (6). The remainder were fattening farms, mixed operations, or feeder pig operations. The type of operation is significant because it has a direct effect on the risk associated with importation of breeding swine, swine semen, and pork.

Incidence of disease in adjacent countries is a factor which influences disease spread. Outbreaks of CSF have occurred sporadically in countries adjacent to the EU (6). Adjacent countries known to have had outbreaks of CSF within the past year include Albania, Czech Republic, Slovenia, Croatia, Poland, Bulgaria, Slovakia, and Latvia. In Poland, disease spread to domestic swine has been attributed to contamination from wild swine migrating freely in Europe.

EU Control of CSF Spread

Animal health regulations within the EU are harmonized for all member states. The EU system of internal controls is described in various EU Council Directives (7). These describe regulations relevant to the movement of animals and animal products. Controls described in these directives include veterinary checks at the points of origin and points of destination. The current system replaced veterinary checks at borders which were abolished when the Internal market was formed.

Notification of OIE list A diseases is compulsory in the EU. Laboratory tests for CSF are performed on all sick swine if the disease or another notifiable disease of swine is suspected. Tests are required for wild boar that are shot or found dead.

As previously mentioned, in addition to the movement controls, the EU has a stamping out policy for CSF. Components of the EU's stamping out policy, such as the requirement to define protection and surveillance zones around an outbreak to prevent the disease from spreading to other areas, are relevant to this assessment. The minimum requirements established by the EU directives for stamping out an outbreak include definition of a protection zone with a radius of 3 kilometers from the outbreak location and a surveillance zone surrounding the protection zone of at least 10 additional kilometers. In actual practice, the size and duration of these zones frequently exceed these minimum requirements, providing additional protection against spread.

Special control measures are implemented in protection and surveillance zones. Premises within the protection zone are prohibited from moving swine outside the zone for at least 30 days. All

premises are inspected, and all animals are depopulated on infected premises. Premises within the surveillance zone are prohibited from moving swine outsize the zone for 15 days. If outbreaks spread to new areas (as was observed in spread of the disease from The Netherlands to Spain in 1997), new protection and surveillance zones are established. Movement controls are established, and inspection and depopulation are initiated. In addition to these control measures, the EU has an extensive trace-back policy.

Various aspects of the effectiveness of the EU's system of control were analyzed in the risk assessment. Specifically, the analysis addressed the potential failure of the stamping out process.

Geographic Scope of the Risk Assessment:

APHIS excluded certain regions of the EU from the analysis because they had been defined previously as low risk areas for CSF. It also excluded certain areas which it considered to have extremely high levels of risk.

The region excluded as low risk consisted of the United Kingdom including Northern Ireland, the Republic of Ireland, Sweden, Finland, and Denmark. APHIS considers these Member States as low risk because they are currently recognized as free of CSF: The analysis presented in this report, therefore, does not address the CSF risk associated with these Member States (Figure 2).

The regions excluded as high risk are regions which APHIS considers to be affected by CSF. These are regions where there has been one or more outbreaks of CSF in domestic swine in the past six months, or the area is known to have endemic disease in wild boars which there is not a history of repeated outbreaks in which disease appeared to be transmitted from wild swine to domestic swine. The high risk regions are the following:

1. Germany: The Kreis Vechta in the landers of Lower Saxony, the Kreis Warendorf in the landers of North-Rhine Westfalen, and the Kreis Altmarkkreis Salzwedel in the landers of Saxony-Anhalt. (Note: A landers is a Federal State and a Kreis is roughly equivalent to a U.S. county.)

2. Italy: The Island of Sardinia and the regions of Piemonte and Emilia-Romagna.

The geographic boundaries of the CSF-affected regions in Germany and Italy that APHIS excluded from the scope of this risk assessment were based on an administrative unit with both effective veterinary oversight of animal movement, and, in association with federal authority if necessary, local responsibility for animal disease control. These administrative units vary from Member State to Member State.

As regions considered affected by CSF, the import requirements would be those which APHIS has applied historically to CSF-affected regions or countries.

Breeding Swine Model

The evaluation of live swine focused on breeding swine (i.e., seed stock swine) since other live swine from the EU (such as feeder pigs) are not likely to be imported into the U.S. due to prohibitive transportation costs. The risk associated with live swine other than breeding swine was not evaluated in this analysis.

For the breeding swine model, a binomial probability distribution (9, 10, 11) was used to estimate the risk associated with the importation of CSF in live swine form the EU. A model was constructed to estimate the probability that an undetected infected breeding swine from undetected infected herds could be selected for export to the United States.

The nested probability approach presented in this report has not been independently reviewed. The USDA Office of Risk Assessment and Cost Benefit Analysis has reviewed and approved this risk assessment while the risk assessment methodology used in this report is under independent review.

Import Assumptions for the Starting Case

Consistent with OIE guidelines for CSF and the current regulations codified in the Code of Federal Regulations (17), the United States require that the veterinary authorities of the exporting country provide certification of the origin of an animal or animal product to be exported and ensure that the animal or animal product has not been exposed to a contagious disease during shipment from the point of origin to the point of embarkation. For the United States, these standard requirements, reflected in federal regulations (17), were enacted to protect our international trade. These originating statutes (identified in the regulations) were enacted to prevent export of animals that were not born or resided in the United States and to ensure the importing country that these animals were not unknowingly exposed to a contagious disease prior to shipment.

In addition, export OIE guidelines are applied to movement of animals and animal products within the EU (7). APHIS assumed these standard requirements would already be imposed and, therefore, they were assumed as a starting point for breeding swine imports from the EU.

The EU directives describe mandated procedures to follow when a OIE list A disease has been detected. A stamping out policy is implemented where an infected area, i.e., the protection zone, and an area surrounding the infected area where increased surveillance is practiced, i.e., the

surveillance zone, are established. All movement of animals out of these two zones is prohibited and depopulation of animals in the protection zone is initiated. During outbreaks of CSF in the Netherlands in 1996 and 1997, spill over of infection into free areas outside of the protection zone, and in some cases, outside of the surveillance zone occurred. In each instance, new protection and surveillance zones were established to encompass the newly detected cases. In effect, both the protection and surveillance zones grew larger in diameter.

Despite these measures, it appeared that attempts to contain the spreading disease by The Netherlands officials were unsuccessful. If the analysis failed to account for the unsuccessful attempts to control disease in The Netherlands, the risk to the United States of importing CSF virus in breeding swine could be underestimated. Therefore, given the outbreak history which occurred in The Netherlands, the risk assessment team included estimates of the potential failure of the EU stamping out policy as "a worse case" event in the model. To estimate this event, APHIS defined the risk associated with an undetected outbreak as a case or cases of CSF infection occurring outside of an established protection or surveillance zone. Both the protection and surveillance zones were considered as an endemic areas for CSF. In addition, Spain provided evidence (6) that the outbreaks experienced in several provinces in 1996 and 1997 were traced back to exports of fattening swine from The Netherlands.

Other import assumptions relate to current US Regulations for export of swine from the EU, which include quarantine and testing for brucellosis, pseudorabies, and tuberculosis diseases prior to shipment. Although the quarantine requirements would serve as an additional mitigation for CSF since animals are observed by a veterinary official of the exporting country during the quarantine period, these export conditions were not considered in this risk assessment. Our concern was that future changes in these regulations might be inappropriate for CSF. Our objective in this risk assessment was to define the potential risk to the US Swine herd associated with export of CSF infected live breeding swine.

Breeding Swine: Scenario Tree and Mathematical Model

The binomial distribution is useful for evaluating the probability of a specified outcome when only two outcomes, defined as success and failure, are possible. For this analysis, success is the selection and export of a healthy animal not infected with CSF; failure is the export of a CSF-infected animal. A multi-level, nested binomial is used because the identification of animals for export includes two levels of selection: first, one or more breeding herds are selected, and then, second, one or more animals are selected from each breeding herd. A simple, single-level, binomial distribution is inadequate to model this process because it is unable to account for the clustering within identifiable herds of the animals selected for export and the similar clustering of infected animals. The multilevel, nested binomial probability distribution has previously been used to evaluate the predictive value of diagnostic testing (12), validate disease surveillance

programs (13), evaluate the probability of success or failure of disease eradication programs (14), and has been proposed for evaluating the level of sanitary risk associated with the importation of animals and animal products (18).

Figure 4 shows a scenario tree of the pathway for potential introduction of CSF into the United States from the EU via live breeding swine. Branch points are shown to facilitate conceptualization of the mathematical model. Because of the clustering effect described above, the probability of importing one or more infected animals cannot be calculated simply by multiplying the probabilities at each branch point in the tree.

The initiating event is the request to export live breeding swine to the United States. Branch point 1 represents the probability of selecting an infected herd from which to export breeding swine. Branch point 2 represents the probability of selecting an infected animal, given that an infected herd has been selected.

Derivation of the Mathematical Model

The multi-level, nested binomial distribution determines the annual probability that one or more breeding swine selected for export are infected with CSF. The distribution is derived as follows:

Let **g** = the number of undetected CSF infected herds in the EU, given that undetected CSF exists in the EU within regions eligible to export breeding swine. (Eq. A)

Let **h** = the total number of breeding herds in the EU. (Eq. B)

Then, **g/h** = the probability that a given EU breeding herd has undetected CSF, given that undetected CSF exists within the EU. (Eq. C)

Assuming that the selection of breeding herds for export is random, (1 - **g/h**) = the probability that a randomly selected breeding herd does not have undetected CSF, given that undetected CSF exists within the EU. (Eq. D)

Let **i** = the probability that an individual animal is CSF-infected, given that the breeding herd is CSF-infected. (Eq. E)

Assuming that breeding swine within a breeding herd are randomly selected for export, then (1 - **i**) = the probability that a randomly selected animal is not CSF infected, given that the herd of origin is CSF infected. (Eq. F)

Let **f** = the number of animals selected for export from any given breeding herd. (Eq. G)

Then, combining Eq. F and Eq. G, $(1 - \mathbf{i})^f$ = the probability that f animals selected for export from any given infected breeding herd are all not CSF infected. (Eq. H)

Multiplying Eq. C and Eq. H, $g/h(1 - \mathbf{i})^f$ = the probability that a given breeding herd is CSF infected and that all f animals selected from that herd are not CSF infected. (Eq. I)

Adding Eq. D and Eq. I, $[(1\text{-}\mathbf{g/h}) + \mathbf{g/h}(1 - \mathbf{i})^f]$ = the probability that a randomly selected breeding herd is either not CSF infected or that it is infected and all the animals selected from that herd are not infected. (Eq. J)

Let **d** = the number of breeding swine shipments per year. (Eq. K)

Let **e** = the number of breeding herds per shipment. (Assume that the number of breeding herds per shipment is constant.) (Eq. L)

Then **de** = the number of breeding herds selected per year. (Eq.M)

Let **b** = the number of weeks that CSF infection remains undetected in EU breeding herds in a typical year. (Eq. N)

Then, assuming that breeding swine shipments are randomly distributed throughout the year, multiplying Eq. M by Eq. N and dividing by the number of weeks in a year, **deb**/52 = the number of breeding swine herds from which shipments originate during a time period when CSF exists undetected in EU breeding herds in a typical year. (Eq. O)

Exponentiating Eq. J by Eq. O, $[(1\text{-}\mathbf{g/h}) + \mathbf{g/h}(1 - \mathbf{i})^f]^{(\mathbf{deb}/52)}$ = the probability that all **deb**/52 herds selected for the export of animals and originating during a time period when CSF exists undetected in EU breeding herds in a typical year either originate from herds that are not CSF infected or, if the herd is CSF infected, contain only CSF-uninfected animals. (Eq. P)

Subtracting Eq. P from 1, $1 - \{[(1\text{-}\mathbf{g/h}) + \mathbf{g/h}(1 - \mathbf{i})^f]^{(\mathbf{deb}/52)}\}$ = the inverse of Eq. P = the probability that among the **deb**/52 herds selected for export during a period when CSF exists undetected in EU breeding herds, there exist one or more herds with undetected CSF infection and that one or more infected animals have been selected for export from such herds. (Eq. Q)

More simply stated, equation Q is the annual probability of importing one or more CSF infected breeding swine.

Input Values Assigned to Variables for the Breeding Swine Model

The results from the breeding swine model were obtained using the input values defined below.

Evidence for Equation Variables:

g (Number of undetected, CSF-infected, breeding farms eligible to supply animals for export, given that undetected CSF exists in the EU)

g= 0.5

In 1997 and 1998 only one breeder farm engaging in export sales became infected with CSF outside of any established restriction zones in the EU (6, 15). The value of 0.5 is therefore the average annual number of undetected breeder farms in the EU for these two years.

h (Number of breeding herds eligible for export in the EU)

To adjust for differences in the number of breeding herds reported in each EU Member State, **h** = was calculated using a uniform distribution based on 1,100 to 1,200 breeding operations (mean of 1,150) in the Netherlands. The mean value resulting from the distribution was 14,290. For this assessment, the mean was used as an estimate of the average number of breeding herds that could exist in any given region at any given time (6, 15).

b (Number of weeks that CSF remains undetected in EU breeding herds per year, given that undetected CSF exists in the EU)

b = The number of weeks CSF infection remains undetected (the "risky" period as defined in the Introduction) varies from one Member State to another as well as, over time, within each Member State (6). Risky periods for EU CSF outbreaks in 1997 are estimated to be: (1) Netherlands, 35 days, (2) the Lerida province in Spain, 53 days, (3) Segovia, Madrid, and Toledo provinces in Spain, 7 to 21 days, most likely 10 days, (4) Belgium, 42 days, (5) Italy, 7 to 21 days, most likely 15 days, (6) Germany, 7 to 21 days, most likely 10 days. These data were fitted to distributions and mean values calculated.

d (Number of breeding swine shipments per year)

d = 34

Based on import records of APHIS, VS, NCIE, the United States received 34 shipments of breeding swine from the EU during 1997 (8). For purposes of the analysis, we assumed that increased numbers of animals shipped would be minimal; therefore, we used the known number of shipments (Table 2).

Table 2. The Known Number of Shipments and Number of Animals Each Shipment Exported to the United States in 1997 (8).

Member State	Number of Shipments	Total Number of Swine
Denmark	9	1,116
Finland	2	12
Sweden	3	23
United Kingdom	20	148
Total	34	1,299

e (Number of breeding herds per shipment)

e = 1

f (Number of animals selected for export from any given breeding herd)

The data for 34 shipments (Table 2, above) were fitted to a distribution. The distribution for the number of swine per shipment was very skewed. The maximum number per shipment was 437, and the minimum number was 1. Most shipments consisted of between 1 and 10 animals. The geometric mean of this distribution is 6.125. APHIS staff used a value of 6.

i (Probability that an individual animal is CSF-infected, given that the herd is CSF-infected)

i = Triangular distribution (0.05, 0.15, 0.40)

Simulation Results of the Starting Breeding Swine Model

Two types of numerical results are presented below: (1) likelihood estimates showing the annual likelihood of importing CSF into the United States under the conditions described, and (2) the expected frequency of one or more (1+) CSF outbreaks in the United States.

A summary of the results of the starting risk estimation (breeding swine simulation #1) is shown below. The results are presented in terms of the minimum, maximum, mean (average), mode (most likely), and median (50th percentile) values of the distributions. The mode or median of the distribution is generally considered a better representation of the central tendency of the distribution than the mean when the distributions are skewed.

Summary of Results from Breeding Swine Simulation

	Starting Likelihood of one or more incursions per year	Expected frequency of incursions (expect at least one incursion every "x" years)
Minimum	9.78E-06	102,249
Maximum	2.05E-04	4,878
Mean	5.98E-0 5	16,722
Most likely	2.97E-05	33,670
Median	4.20E-05	23,810

Under starting conditions, the most likely outcome estimated was that at least one outbreak should be expected every 33,670 years.

Swine Semen Model

The objective of this portion of the analysis was to estimate the probability of undetected infection entering the United States via swine semen imported from the region of the EU defined in this report. The analysis performed was a variation of the breeding swine model.

Import Assumptions for the Starting Case

Most assumptions for the starting case in the swine semen model are the same as those discussed previously for the breeding swine model (pages 8 and 9 of this report) and will not be repeated here.

The starting assessment for swine semen also reflects some level of mitigation exerted by routine procedures for swine semen currently operating in the EU. These conditions are described in EU regulations, Commission Decision 90/429/EEC (7) and are binding on all Member States.

These regulations promulgate certification requirements for semen donors which are more stringent than for other types of swine for transport between Member States. The observation that only a single CSF outbreak occurred in an EU-approved swine semen center whereas 103

outbreaks were observed overall (6) suggests that such control procedures reduce the level of risk associated with donor boars in comparison to swine raised for other purposes.

Specifically, the EU regulations require that animals must have been accompanied by a veterinary certificate of origin, that they have not been given the opportunity to commingle with swine from CSF-affected areas, and that semen must originate from a collection center approved for export by the veterinary services of the national government of the EU Member State in which the collection center is located. Donor boars are held in isolation for at least 30 days prior to entering the semen collection center and test results for CSF using a test approved by OIE and performed during that 30 day period must be negative. Therefore, the values used in the swine semen assessment were derived from epidemiological data on animals subject to these restrictions.

A second assumption made in the swine semen model relates to the incubation period for CSF, which OIE considers to be 40 days. APHIS incorporated this into an additional 40 day holding time for boars after semen collection during which animals were observed for clinical signs of disease into a mitigation strategy. The group assumed further that this additional 40 day holding time alone would not influence the risk of CSF transmission. Therefore, the group included clinical observation during the 40 day holding period prior to release of semen for shipment in the assessment to mitigate the risk further.

Other import requirements defined in current US Regulations for export of swine semen from the EU include quarantine and testing for brucellosis, pseudorabies, and tuberculosis prior to shipment. Donor boars are required to be quarantined for a minimum of 60 days before collection of semen for export to the United States, and must be tested twice for brucellosis, tuberculosis, and pseudorabies with negative results. Tuberculin tests must be conducted with an interval of at least 60 days between tests, and the second test must be conducted no sooner than 30 days following collection of the semen. The semen is frozen for a minimum of 30 days until the second test is performed. However, if the donor boar has resided in the semen collection center for at least 6 months and has been tested twice during that time period for these three diseases and was found negative, semen may be exported as fresh semen. Although these quarantine requirements would serve as an additional mitigation for CSF since animals are observed by a veterinary official of the exporting country during the quarantine period, these export conditions were not considered in this risk assessment. In considering the risk of the introduction of CSF into the United States through swine semen, we believe it is necessary to assume that quarantine periods do not exist for other diseases, because it is possible that regions currently affected by these other diseases could one day be considered free of them.

An additional assumption was that, given the economic value of the donor boars held in the semen center, it was assumed that any sign of poor health would be detected.

Swine Semen: Scenario Tree and Mathematical Model

The binomial distribution is useful for evaluating the probability of a specified outcome when only two outcomes, defined as success and failure, are possible. For this analysis, success is the selection and export of a healthy donor boar semen not infected with CSF; failure is the export of CSF-infected semen. A multi-level, nested binomial is used because the identification of boars for export of semen includes two levels of selection: first, one or more semen collection centers are selected, and then, second, one or more donor boars are selected from each collection center. A simple, single-level, binomial distribution is inadequate to model this process because it is unable to account for the clustering within identifiable herds of the animals selected for export and the similar clustering of infected animals. The multilevel, nested binomial probability distribution has previously been used to evaluate the predictive value of diagnostic testing (12), validate disease surveillance programs (13), evaluate the probability of success or failure of disease eradication programs (14), and has been proposed for evaluating the level of sanitary risk associated with the importation of animals and animal products (18).

Figure 5 shows a scenario tree of the pathway with three branch points for potential importation of CSF into the United States. The scenario illustrates the basic underlying thought process for the model. In this tree, the initiating event is the request to import swine semen. Branch point 1, which represents the probability of selecting an infected semen center, and Branch point 2, which indicates the probability of selecting an infected boar, are considered in the starting analysis. Branch point 3 represents the mitigating step of observing for clinical signs during the 40 day holding period after semen is collected.

The equation for "**Q**", i.e., the probability that an undetected infection might enter the US in the absence of import requirements other than those included in the model assumptions is presented also. For the starting analysis, the probability of selecting an infected semen center from which to import swine semen (Branch point 1) was multiplied by the probability of selecting an infected donor boar (Branch point 2), should an infected semen center be inadvertently selected from which to export.

The effect of observing the animals clinically during the 40 day holding period after entry into the collection center (Branch point 3) was assessed as a mitigating factor.

<u>Derivation of the Mathematical Model</u>

The multi-level, nested binomial distribution determines the annual probability that one or more swine semen centers selected for export of semen are infected with CSF. The distribution is derived as follows:

Let **g** = the number of undetected CSF infected swine semen centers in the EU, given that undetected CSF exists in the EU within regions eligible to export swine semen. (Eq. A)
Let **h** = the total number of swine semen centers in the EU. (Eq. B)

Then, **g/h** = the probability that a given EU swine semen center has undetected CSF, given that undetected CSF exists within the EU. (Eq. C)

Assuming that the selection of swine semen centers for export is random, (1 - **g/h**) = the probability that a randomly selected swine semen center does not have undetected CSF, given that undetected CSF exists within the EU. (Eq. D)

Let **i** = the probability that an individual donor boar is CSF-infected, given that the swine semen center is CSF-infected. (Eq. E)

Assuming that the donor boars from a swine semen center is randomly selected for collection and export of semen, then (1 - **i**) = the probability that a randomly selected donor boar is not CSF infected, given that the swine semen center is CSF infected. (Eq. F)

Let **f** = the number of donor boars selected for export of semen from any given swine semen center (Eq. G)

Then, combining Eq. F and Eq. G, $(1 - \mathbf{i})^f$ = the probability that f donors selected for collection and export of semen from any given swine semen center are all not CSF infected. (Eq. H)

Multiplying Eq. C and Eq. H, $g/h(1 - \mathbf{i})^f$ = the probability that a swine semen center is CSF infected and that all **f** donor boars selected from that center are <u>not</u> CSF infected. (Eq. I)

Adding Eq. D and Eq. I, $[(1-\mathbf{g/h}) + \mathbf{g/h}(1 - \mathbf{i})^f]$ = the probability that a randomly selected swine semen center is either not CSF infected or that it is infected and all the donor boars selected from that center are <u>not</u> infected. (Eq. J)

Let **d** = the number of swine semen shipments per year. (Eq. K)

Let **e** = the number of swine semen centers per shipment. (Assume that the number of swine semen centers per shipment is constant.) (Eq. L)

Then **de** = the number of swine semen centers selected per year. (Eq.M)

Let **b** = the number of weeks that CSF infection remains undetected in EU swine semen centers in a typical year. (Eq. N)

Then, assuming that swine semen shipments are randomly distributed throughout the year, multiplying Eq. M by Eq. N and dividing by the number of weeks in a year, **deb**/52 = the number of swine semen centers from which shipments of semen originate during a time period when CSF exists undetected in EU swine centers in a typical year. (Eq. O)

Exponentiating Eq. J by Eq. O, $[(1-\mathbf{g}/\mathbf{h}) + \mathbf{g}/\mathbf{h}(1 - \mathbf{i})^{\mathbf{f}}]^{(\mathbf{deb}/52)}$ = the probability that all **deb**/52 swine semen centers selected for the export of semen and originating during a time period when CSF exists undetected in EU swine semen centers in a typical year either originate from swine semen centers that are not CSF infected or, if the center is CSF infected, contain only CSF-uninfected boars. (Eq. P)

Subtracting Eq. P from 1, $1 - \{[(1-\mathbf{g}/\mathbf{h}) + \mathbf{g}/\mathbf{h}(1 - \mathbf{i})^{\mathbf{f}}]^{(\mathbf{deb}/52)}\}$ = the inverse of Eq. P = the probability that among the **deb**/52 centers selected for export of semen during a period when CSF exists undetected in EU swine semen centers, there exist one or more centers with undetected CSF infection and that one or more infected donor boars have been selected for export of semen from such centers. (Eq. Q)

More simply stated, equation Q is the annual probability of importing one or more CSF infected swine semen shipments.

Input Values Assigned to Variables for the Starting Swine Semen Model

The results from the swine semen model were obtained using the input values defined below.

<u>Evidence for Equation Variables</u>

g - Proportion of undetected infected semen centers in 1997 and 1998:

g = 0.5

In 1997 and 1998 only one EU approved swine semen center outside of established protection and surveillance zones became infected with CSF. The value of 0.5 represents the average annual number of undetected breeder farms in the EU for these two years (6, 15)

h - Average number of swine semen centers:

h = 138 (6)

The EU reported 138 approved swine semen centers in the Member States, i.e., 6 in the Netherlands, 43 in Spain, 12 in Belgium-Luxembourg, 27 in Germany, 6 in Italy, 3 in Portugal, 0 in Greece, 5 in Austria, and 36 in France.

i - Proportion of infected animals in an infected semen center:

i = Triangular distribution (0.05, 0.15, 0.40)

The triangular distribution was suggested by Dr. J. M. Westergaard of the European Commission. Indirect reports suggest that value may be extremely variable, i.e., 25-100% depending on circumstances (16).

b- Number of weeks infection remains undetected:

b= The number of weeks CSF infection remains undetected (the "risky" period as defined in the Introduction) varies from one Member State to another as well as within each Member State (6). Risky periods for EU CSF outbreaks in 1997 are estimated to be: (1) Netherlands, 35 days, (2) the Lerida province in Spain, 53 days, (3) Segovia, Madrid, and Toledo provinces in Spain, 7 to 21 days, most likely 10 days, (4) Belgium, 42 days, (5) Italy, 7 to 21 days, most likely 15 days, (6) Germany, 7 to 21 days, most likely 10 days. These data were fitted to distributions and mean values calculated.

d - Number of shipments annually:

d = 53 (8)

Historical data from the APHIS Import Tracking System were used to evaluate the number of doses of EU swine semen that may be imported into the United States. In 1994, the United States imported 700 doses of swine semen from Denmark. In 1995, the United Stated imported 781 doses of swine semen from France. In 1996, the United States imported 1,830 doses of swine semen from the United Kingdom. No other imports of EU swine semen were recorded during these years and no swine semen imports were recorded in 1997 or 1998 (APHIS, Import Tracking System). In 1994, 1995, 1996, and 1997 the United States imported 775, 750, 850, and 1,800 doses respectively of swine semen from Canada (where European Union genetics have been incorporated into some lines). In 1998, the United States imported 600 doses of swine semen from Canada (APHIS, Import Tracking System). APHIS judged the number of doses to be zero, 800, and 1800 for minimum, most likely, and maximum values, respectively. The most likely number of shipments was estimated to be 800/15 = 53. APHIS recognizes this variable

may be under assessed and seeks input on the development of more accurate data. There were a total of 15 shipments from 1994 to 1998.

e - Average number of swine semen centers per shipment:

For the starting model, this value was calculated using the time period during which undetected infection may be present in the region (risky time period). It was assumed that all semen in one shipment would originate from one swine semen center. To include the risky time period in the model, **e** was set equal to 1/**a**. The value of **a** was calculated by

a = (d*b)/52; where 52 is the number of weeks in a year.

f - Number of boars selected per semen center per shipment:

f = 1.

Simulation Results of the Starting Swine Semen Model

Two types of numerical results are presented below: (1) probability estimates showing the annual possibility of importing CSF into the United States under the conditions described, and (2) the expected frequency of one or more (1+) CSF outbreaks in the United States. The latter result is presented to provide some perspective on the meaning of the annual probability estimates.

A summary of the results of the swine risk estimation (swine semen simulation #1) is presented in terms of the minimum, maximum, mean (average), mode (most likely), and median (50th percentile) values of the distributions. The mode or median of the distribution is generally considered a better representation of the central tendency of the distribution than the mean when the distributions are skewed.

Summary of the Results of the Starting Swine Semen Simulation Model

	Starting likelihood of one or more incursions per year	Expected frequency of incursions (expect at least one incursion every "x" years)
Minimum	1.90E-04	5,263
Maximum	1.44E-03	694
Mean	7.25E-04	1,379
Most likely	5.43E-04	1,842
Median	6.91E-04	1,447

The results indicated that the most likely case was that importation of swine semen under the starting conditions would be expected to result in at least one outbreak in 1,842 years.

Mitigated Swine Semen Model Construction

APHIS proposes a single risk mitigating requirement for imported semen. This requirement is that semen donor boars must be held and observed for a minimum of forty days before their semen is used. The rationale for the requirement is that holding boars for forty days provides a reasonably adequate period of time to observe clinical signs of disease and detect CSF if in fact the boars were exposed to and infected with CSF shortly before semen collection. APHIS believes the requirement neither imposes an undue burden on exporters nor unreasonably interferes with trade.

A mathematical model to determine the increment of risk reduction achieved by the requirement was developed.

Derivation of the Mathematical Model

A binomial distribution was used. For this part of the assessment, APHIS seeks input and guidance for improving the model.

Let $\mathbf{m}$ = the probability that a CSF-infected boar will show clinical signs sufficient to result in diagnosis of the disease within forty days of semen collection. (Eq. A)

Then $\mathbf{(1\text{-}m)}$ = the probability that a CSF-infected boar will not show clinical signs sufficient to result in diagnosis of the disease with forty days of semen collection. (Eq. B)

Let $\mathbf{k}$ = the number of infected boars from which semen is collected for export and which must be held for forty days of observation. (APHIS notes that, given that at least one boar is CSF-infected, not all boars held for observation are necessarily CSF-infected. Thus, k does not necessarily equal the number of boars held for observation.) (Eq. C)

Then, exponentiating Eq. B by Eq. C, $\mathbf{(1\text{-}m)^k}$ = the probability that all k boars will not show clinical signs sufficient to result in diagnosis of the disease within forty days of semen collection. (Eq. D)

Subtracting Eq. D from 1, $\mathbf{1 - (1\text{-}m)^k}$ = the inverse of Eq. D = the probability that one or more boars will show clinical signs sufficient to result in diagnosis of the disease within forty days of semen collection. (Eq. E)

Evidence for Equation Variables

m (the probability that a CSF-infected boar will show clinical signs sufficient to result in diagnosis of the disease within forty days of semen collection)

A uniform distribution was used. APHIS staff estimated a minimum value of 0.7 and a maximum value of 0.8.

k (the number of boars from which semen is collected and which are held for observation)

This value was set to 1, representing collection of semen from a single animal held alone. For this analysis, we set k = 1 to exclude the sentinel effect of other animals held together.

Summary of the Results of Mitigated Swine Semen Simulation

	Likelihood of one or more incursions per year with described import restrictions	Expected frequency of incursions (expect at least one incursion every "x" years)
Minimum	1.04E-09	961.5 million
Maximum	3.22E-04	3,106
Mean	4.18E-05	23,923
Most likely	3.88E-09	257.7 million
Median	2.57E-05	38,911

Adding clinical observation to the 40 day holding period increased the most likely introduction of CSF from swine semen into the US from every 1,842 years to one chance in approximately 260 million years.

Pork Model

The assessment determined the probability that the importation of pork from the EU will result in an outbreak of CSF in the United States. For the purposes of the analysis, pork is modeled as a single aggregate commodity. Possible differences among pork products, in disease risk and in the relative likelihood of their being used in waste feeding, that would warrant disaggregation are not known.

Previous APHIS risk assessments, for example the assessment on importing beef from Argentina, have modelled the quantity of contaminated product likely to be imported. In this assessment, we extend the model to describe the probability of a disease outbreak. We believe the primary pathway by which U.S. domestic livestock would be exposed to pathogens in imported food commodities is via the feeding of food waste to swine. The dissemination of imported food commodities within the U.S. food marketing system, however, is extraordinarily complex, as are the pathways by which food waste is collected and disposed. In our model, every restaurant box of imported pork is assumed to represent a statistically independent opportunity to transmit CSF to domestic swine. This assumption is not likely correct and may substantially magnify the calculated frequency of disease outbreaks. We recognize the model used here oversimplifies a complex sequence of events and seek input on the development of more accurate models for predicting disease risk due to waste feeding.

Import Assumptions for the Starting Case

The assessment assumes that all swine slaughtered to produce pork for export to the United States from the EU are in compliance with EU regulations for the control and eradication of CSF.

This assumption reflects APHIS's belief that pork for export to the United States is produced using EU's standard operating procedures for pork production.

The assessment assumes that swine slaughtered to produce pork for export to the United States are slaughtered in compliance with the requirements of USDA-Food Safety and Inspection Service (17). These requirements include ante-mortem and post-mortem inspection. Although the impact of these requirements was not considered in the risk assessment, APHIS believes that these requirements would further reduce the quantity of contaminated pork likely to be exported to the United States.

The assessment assumes that if a CSF-infected animal is slaughtered, then all of the meat from that animal is contaminated with virus. This is a worst case assumption and magnifies the calculated probability of a CSF outbreak.

Pork: Scenario Tree and Mathematical Model

Figure 6 shows a scenario tree describing the primary pathway by which APHIS believes contaminated pork would be exported to the United States. The initiating event is the slaughter of pigs for production of pork for export to the United States. Branch point 1 represents the probability that any individual slaughtered pig is contaminated with CSF. Multiplier N is the number of boxes of pork per pig slaughtered. Branch point 2 represents the probability that imported pork is used by restaurants. Branch point 3 represents the probability that restaurants

discard uncooked pork trimmings in their waste materials. Branch point 4 represents the probability that the restaurant waste material is collected by a swine producer. Branch point 5 represents the probability that the waste product containing imported pork is inadequately cooked by the waste feeder. Branch point 6 represents the probability that inadequately cooked waste containing CSF-contaminated pork fed to swine results in a CSF outbreak.

Derivation of the Mathematical Model

Let Q = the number of pigs slaughered to provide pork for export the United States.

Let P = the probability that any given pig is infected with CSF.
Then Q x P = the number of pigs slaughtered to provide pork for export to the United States that are infected with CSF.

Let N = the number of boxes of pork per slaughtered pig.
Then Q x P x N = the number of boxes of pork containing CSF-contaminated pork

Let F2 = the fraction of imported pork used by restaurants. Then Q x P x N x F2 = the number of boxes of CSF-infected imported pork used by restaurants. (We assume that imported pork used by households and institutions represents negligible disease risk because food waste from households and institutions is rarely if ever collected by waste feeders.)

Let F3 = the probability that a box of pork is trimmed by restaurants and the trimmings discarded uncooked in the restaurant waste.

Let F4 = the probability that food waste from any given restaurant is collected by a waste feeder.

Let F5 = the probability that a waste feeder does not cook collected waste sufficiently on site to inactivate any CSF virus that may be present.

> For the probability that the waste feeder does not cook waste sufficiently to inactivate CSF virus, separate distributions were used for licensed versus unlicensed waste feeders. For licensed waste feeders, a triangular distribution was used. APHIS staff estimated a minimum value of 0.4, most likely value of 0.5, and a maximum value of 0.8 for licensed waste feeders. Unlicensed waste feeders would be feeding waste products to swine illegally. For unlicensed waste feeders, it was assumed that all waste would be cooked insufficiently to inactivate CSF virus.
>
> These different distributions for licensed versus unlicensed waste feeders were weighted by the proportion of waste feeders who are licensed versus unlicensed. For the

proportion of waste feeders who are licensed, a triangular distribution was used. APHIS staff estimated a minimum value of 0.9, most likely value of 0.95, and a maximum value of 0.98. This distribution was multiplied by the distribution for the probability that licensed waste feeders do not cook waste sufficiently to inactivate CSF virus. For the proportion of waste feeders who are unlicensed, one minus the triangular distribution for licensed waste feeders was used. The resulting distribution was multiplied by 1 for the probability that unlicensed waste feeders do not cook waste sufficiently to inactivate CSF virus.

The parameter F5 was also adjusted for the proportion of infected waste which may contain an infective dose of CSF virus. The distributions described above were multiplied by a triangular distribution representing this proportion. APHIS staff estimated a minimum value of 0.9, a most likely value of 0.95, and a maximum value of 1 for this proportion.

A separate probability estimate was calculated in the analysis for licensed versus unlicensed waste feeders based on the proportions above. An overall probability estimate was calculated using the following binomial equation: **p=1-[(1-pa)*(1-pb)],** where p is the overall probability of one or more CSF outbreaks per year caused by waste feeders, pa is the probability of one or more outbreaks per year caused by licensed waste feeders and pb is the probability of one or more outbreaks per year caused by unlicensed waste feeders."

Let F6 = the probability that CSF-contaminated food waste fed to swine causes an outbreak of CSF.

Therefore, APHIS calculated the probability of one or more outbreaks of CSF per year caused importation of CSF-infected meat and not properly cooked by waste feeders as:

$$\mathbf{P(x) = 1 - \{[1-(F3 \times F4 \times F5 \times F6)]^{(Q \times N \times P \times F2)}\}.}$$

Evidence for Equation Variables

Q (Number of pigs slaughtered to provide pork for export to the United States)

Q is a derived variable based on the expected quantity of pork imports and the quantity of pork exported from the slaughter of a single pig. The derivation is as follows:

APHIS staff estimated the quantity of pork that is likely to be exported from the slaughter of a single hog . The quantity of pork meat per animal (in pounds) was represented by a

triangular distribution with a minimum value of 150 pounds, most likely value of 160 pounds, and maximum value of 170 pounds. The proportion of meat from an animal that is exported was represented by a triangular distribution with a minimum value of 0.35, a most like value of 0.4, and a maximum value of 0.45. The product of these distributions gives an estimate of the quantity of pork meat (in pounds) exported per hog, which is then multiplied by 0.454 to convert pounds into kilograms.

P (Probability that any individual pig is infected with CSF)

P is a derived variable. The mathematical derivation of P is as follows:

Let P_1 = the number of swine fattening farms in the EU with undetected CSF outside of established restriction zones in 1997. P_1 = 101 (6).

Let P_2 = the total number of swine fattening farms in the region of the EU affected by the proposed rule. P_2 = 719,447. P_2 includes 15,784 farms in the Netherlands, 100,000 in Spain, 8,201 in Belgium, 187,475 in Germany, 256,412 in Italy, 79,900 in Portugal, 14,433 in Greece, and 57,272 in France (20).

Then P_1 / P_2 = the probability that a randomly selected fattening farm in the region of the EU affected by the proposed rule had undetected CSF sometime during 1997.

Let P_3 = the probability that a randomly selected animal is CSF infected, given that it originates on an undetected, CSF-infected, fattening farm. Based on information from the European Commission, P_3 is a triangular distribution with minimum value of .05, most likely of .15, and maximum of .40 (21).

Let P_4 = the probability that a randomly slaughtered animal originating from a farm with undetected CSF in 1997 was shipped during the time period when the farm in fact had undetected CSF. P_4 is equal to the length of time a farm had undetected CSF, measured in days, divided by 365. Based on information from the EU technical team (15), these lengths of time are: 1) Netherlands, 35 days (point estimate) 2) the Lerida province in Spain, 53 days (point estimate) 3) Segovia, Madrid, and Toledo provinces in Spain, 7 to 21 days, most likely 10 days (triangular distribution) 4) Belgium, 42 days (point estimate) 5) Italy, 7 to 21 days, most likely 15 days (triangular distribution) 6) Germany, 7 to 21 days, most likely 10 days (triangular distribution). The time infection remains undetected in the EU is represented by a discrete distribution that was weighted using the number of fattening operations present in each of the Member States. Since different provinces in Spain experienced different lengths of time of undetected infection, the number of fattening operations in the autonomous community where the province was located was

used. The lengths of time of undetected infection are entered into the discrete distribution as either point estimates or triangular distributions.

Then $P = (P_1 / P_2) \times P_3 \times P_4$ = the probability that a randomly selected slaughter pig in the EU is infected with CSF at the time of slaughter.

N (Number of restaurant boxes of exported pork per slaughtered pig)

APHIS has little information on this quantity. A triangular distribution is used based on the estimates of APHIS staff. The minimum value is 4, most likely 7, maximum 8. APHIS staff estimated that the proportion of meat from the infected animals that would be infective. A triangular distribution was used with a minimum value of 0.9, a most likely value of 0.95, and a maximum value of 1. This distribution was multiplied by the distribution for the number of restaurant boxes of exported pork per slaughtered pig.

F2 (Fraction of imported pork used by restaurants)

Based on information obtained from the National Pork Producers Council, a triangular distribution with minimum value of 030, most likely value of 0.40, and maximum value of 0.50 is used (23).

F3 (Probability that restaurants discard uncooked trimmings)

Data on the probability that restaurants discard uncooked pork trimmings is not readily available. APHIS staff discussed this issue with pork industry representatives who stated that the fraction of pork trimmed is small or very nearly zero. Industry representatives stated that restaurant pork is cut and packaged with an intent to eliminate the need for further trimming. Based on this information, APHIS staff assumed a triangular distribution with a minimum value of 0.00001, most likely value of 0.0001, and maximum value of 0.001.

F4 (Probability that restaurant waste is collected by waste feeders)

Based on unpublished research conducted in March, 1998 on the ratio of waste feeders to restaurants, APHIS-VS-CEAH estimates that 2,666 restaurants supply food waste to waste feeders. Census Bureau data for 1992 indicate approximately 430,000 restaurants in the U.S., excluding Hawaii and Alaska. Based on this information, the probability that a given restaurant's waste is collected by waste feeders is 2,666 / 430,000 = 0.006. A triangular distribution is used with a minimum value of .005, most likely value of 0.006, and maximum value of 0.007.

F5 (Probability that waste feeder does not cook waste sufficiently to inactivate CSF virus)

A triangular distribution is used. APHIS staff assumed a minimum value of 0.40, most likely value of 0.50, and a maximum value of 0.80.

F6 (Probability that feeding uncooked waste with CSF virus results in a disease outbreak)

APHIS staff assumed that if uncooked food waste containing CSF virus is fed to pigs, the probability of causing CSF in the pigs is high. For this assessment a point probability of 1 was estimated.

Summary of the Results of Pork Simulation #1 (low volume scenario)

	Starting likelihood of one or more outbreaks per year	Expected frequency of outbreaks (expect at least one outbreak every "x" years)
Minimum	2.11E-07	4,739,336
Maximum	2.82E-04	3,546
Mean	2.42E-05	41,322
Most likely	4.41E-06	226,757
Median	1.61E-05	62,112

Summary of the Results of Pork Simulation #2 (medium volume scenario)

	Starting likelihood of one or more outbreaks per year	Expected frequency of outbreaks (expect at least one outbreak every "x" years)
Minimum	3.48E-07	2,873,563
Maximum	7.70E-04	1,299
Mean	4.80E-05	20,833
Most likely	4.41E-05	22,676
Median	3.19E-05	31,348

Summary of the Results of Pork Simulation #3 (high volume scenario)

	Starting likelihood of one or more outbreaks per year	Expected frequency of outbreaks (expect at least one outbreak every "x" years)
Minimum	8.53E-07	1,172,333
Maximum	1.23E-03	813
Mean	7.12E-05	14,045
Most likely	1.19E-04	8,403
Median	4.84E-05	20,661

Summary

The probability estimates for the breeding swine, swine semen and pork models are presented in the following table (Table 3) for comparison. No mitigations beyond certification of origin and handling were imposed on the starting estimates for the breeding swine and pork models so, for these models, the starting and mitigated values are the same.

Starting and mitigated values are presented for the swine semen model. The mitigation assessed in this model was a 40 day holding period after semen collection during which donor animals were observed for clinical signs.

The results of these assessments will be used to support recommendations to the APHIS Administrator for changes in the regulations.

Table 3
Estimates of Risk in the Breeding Swine, Swine Semen and Pork Risk Assessment Models Associated with the Proposed Rule

	Starting values[1]		*Mitigated values*	
Model	*Likelihood*[2] *=* "Q"	*Frequency* = 1/"Q"	*Likelihood* = "Q"	Frequency = 1/"Q"
Breeding swine[3]	2.97×10^{-5}	33,670	2.97×10^{-5}	33,670
Swine Semen[4]	5.43×10^{-4}	1,842	3.88×10^{-9}	257.7 million
Pork[5]	4.41×10^{-5}	22,676	4.41×10^{-5}	22,676

[1] Starting values were obtained under existing conditions imposed by current EU and APHIS regulations. These include EU control of animal movement and management of outbreaks, including a stamping-out policy. Swine semen originates from donor boars held in isolation for at least 30 days prior to entering a federally inspected semen collection center and tested as negative during that period with a test for CSF approved by the Office International des Epizooties. APHIS regulations require that swine and swine semen be accompanied by a certificate of origin stating that the animals have never lived in a region in which CSF is known to exist; the animals must not have transited such a region unless they were moved directly through it in a sealed means of conveyance with the seal intact at the point of arrival; they must not have been commingled with swine which have been in a region in which CSF is known to exist; and no equipment or materials used in transporting the swine or donor boars may have been used for transporting animals ineligible for export to the US prior to appropriate cleaning and disinfection.

[2] Likelihood is expressed as the possibility of one or more incursions per year under the current EU, APHIS regulations described in footnote 1.

[3] No additional mitigations were assessed for breeding swine.

[4] The mitigating effects of holding semen donor boars and observing clinically for 40 days after semen collection was assessed.

[5] No additional mitigations were assessed for pork.

Limitations of the Analysis

This report describes the results of a risk assessment regarding potential imports of European Union (EU) breeding swine, swine semen, and fresh and frozen pork. The potential hazard of interest is the possible introduction and establishment of classical swine fever (CSF) in the United States.

The analysis incorporates biosecurity procedures in place because of both EU and US regulations regarding the handling of swine and swine products. Should any of these regulations change, the results of this assessment might not apply.

The analysis depends on data submitted by the EU for 1997-1998. Should epidemiological characteristics of CSF in the EU change significantly, the results of this assessment might not apply.

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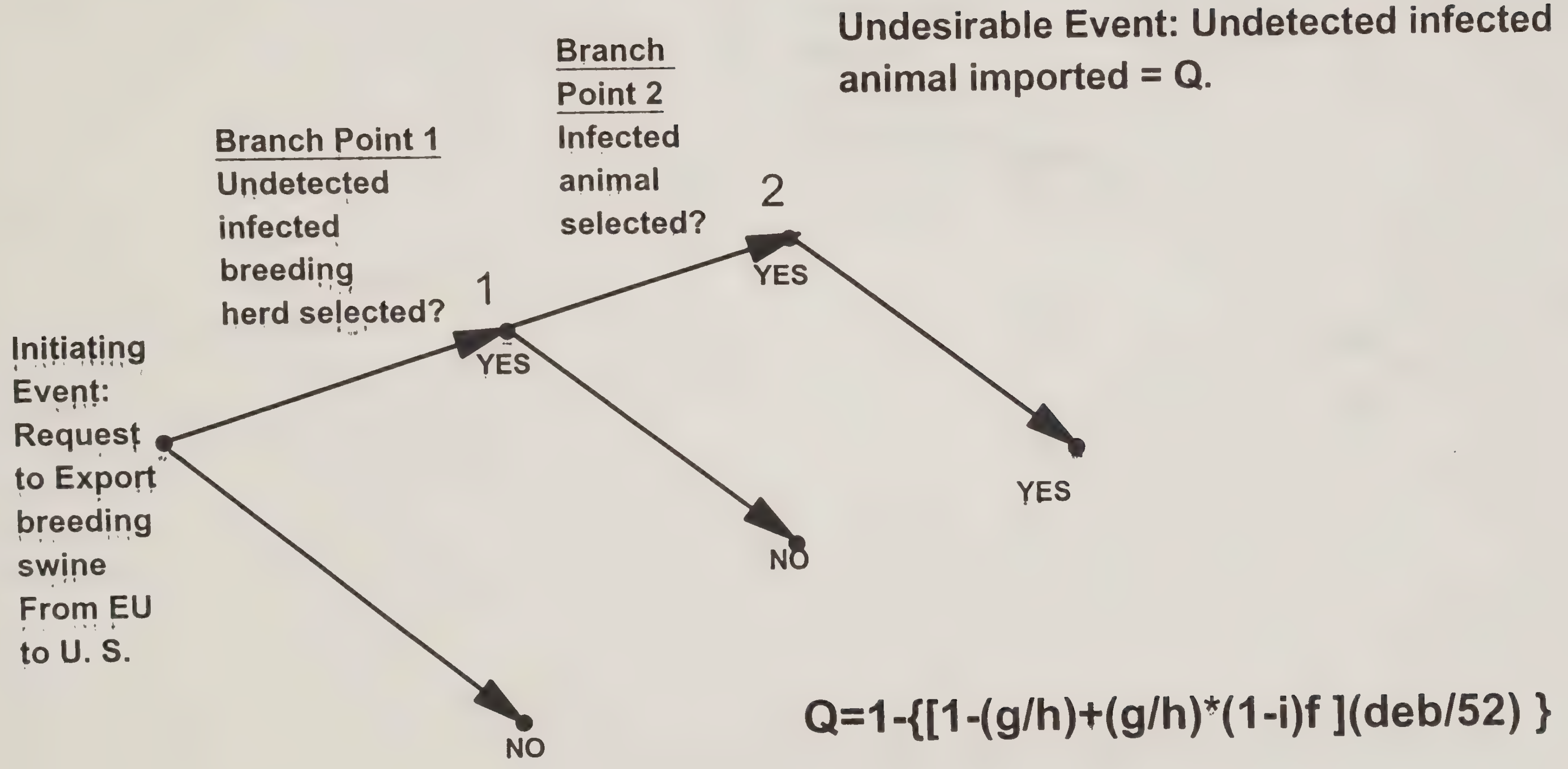
Figure 1. Member States of the European Union

Figure 2. Geographic Scope of the Risk Assessment

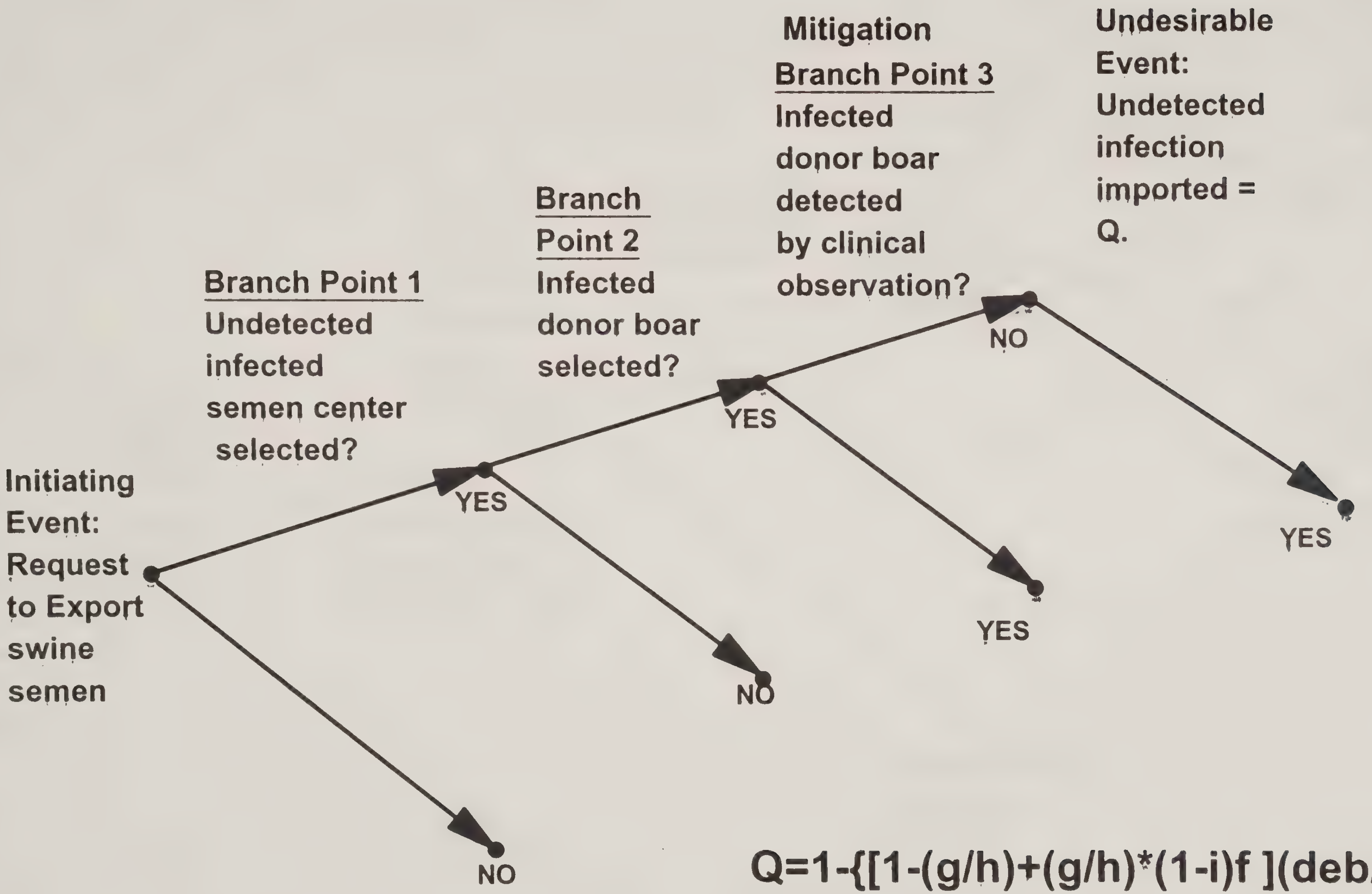
Figure 3. EU Member States Where Infected Herds Were Found outside of Protection and Surveillance Zones during the 1997-98 Outbreaks

Figure 4. Scenario tree of the pathway for potential importation of CSF into the United States - breeding swine model.



$$Q=1-\{[1-(g/h)+(g/h)*(1-i)f\,](deb/52)\,\}$$

Figure 5. Scenario tree of the pathway for potential importation of CSF into the United States - swine semen model.



$$Q=1-\{[1-(g/h)+(g/h)*(1-i)f\,](deb/52)\,\}$$

Figure 6 - Scenario tree of the pathway for potential importation of CSF into the United States - pork model.